JUL 19 2013

510(k) Summary

Special 510(k)

As required by section 807.92(c)

Company Name	Cardiosolutions Inc.
Address	375 West St. West Bridgewater MA 02379 Phone: 781-344-0801 Fax: 781-344-0803
Contact Person	Michele Lucey
Date Prepared	April 24, 2013
Trade Name	Percu-Pro™ Steerable Introducer
Common Name	Steerable Introducer
Classification Name	Steerable Guide Catheter Catheter Introducer
Product Code	DYB, DRA
Regulation #	870.1340, 870.1280
Class	2
Panel	Cardiovascular
Predicate Devices	Percu-Pro™ Steerable Introducer K120086
Device Description	The Cardiosolutions Percu-Pro™ Steerabl e Introducer is provided as a 9Fr and 14Fr Introducer. The set also consists of a dilator (14Fr only), stylet, and tear-away introducer sheath. The steerable introducer is designed to pro vide flexible catheter positioning i n the cardiac anatomy. The steer able introducer provides both proximal tip and distal tip steering and is fitted with a hem ostasis valve to minim ize blood loss duri ng catheter introduction and/or exchange. A sideport with stopcock is provided for air or bloo d aspiration, fluid infusion, blood sampling, and pressure monitoring. The i ntroducer sheath is rei nforced Pebax and the distal tip has a radiopaque marker to im prove fluoroscopic visualization. The device is pro vided in 65 cm working len gths. The device is provided sterile and is intended for single use only. The purpose of this submission is to add an ad ditional device diameter; 9Fr has 65 cm working lengths.

Intended Use	The Percu-Pro™ Steerable Introducer is intended to be used for the introduction of various cardiovascular catheters into the heart, including the left side of the heart through the inter-atrial septum.
Safety and Performance Testing	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. The materials used in the 9Fr Percu-Pro™ Steerable Introducer are identical to the 14Fr Percu-Pro™ Steerable Introducer predicate device. No additional biocompatibility is required. Design verification testing performed on the 9Fr device consisted of mechanical testing conducted in accordance with the ISO 10555 Sterile, single-use intravascular catheters Part 1: General requirements (as amended, 1999, 2004) and in consideration of FDA Guidance on Premarket Notification 510(k) Submission for Short Term and Long Term Intravascular Catheters. The following tests were completed: o Visual Surface Inspection o Dimensional Verification o Corrosion Resistance o Tensile Break Force o Tip Separation Force o Freedom from Leakage Under Pressure o Air Leakage During Aspiration o Luer Hub Compliance o Flexural Fatigue Tolerance o *In Vitro* Simulated Use Studies o Functional Performance Testing o Radiopacity o Shelf Life A summary of the testing performed is included in the 510(k) submission. All test results demonstrate that the properties and performance of the device are suitable for its intended use.
Substantial Equivalence	The 9Fr Percu-Pro™ Steerable Introducer is substantially equivalent to the predicate devices in terms of intended use, design, materials, technology, and function. There are no differences between devices which would raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 19, 2013

Cardiosolutions, Inc.
c/o Michele Lucey
Vice President Regulatory and Quality Compliance
375 West Street
West Bridgewater, MA 02379

Re: K131332
Trade Name: Percu-Pro™ Steerable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB, DRA
Dated: June 21, 2013
Received: June 26, 2013

Dear Ms. Lucey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use Statement

510(k) Number: K131332

Device Name: Percu-Pro™ Steerable Introducer

Indications for Use:

The Percu-Pro™ Steerable Introducer is intended to be used for the introduction of various cardiovascular catheters into the heart, including the left side of the heart through the inter-atrial septum.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)